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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,461	09/10/2003	Christopher J. Calhoun	MA9758P	4950

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EXAMINER	
HAGOPIAN, CASEY SHEA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,461	CALHOUN, CHRISTOPHER J.	
	Examiner	Art Unit	
	Casey Hagopian	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *12-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of applicant's Response to Restriction Requirement filed 11/16/2005.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 8-10 of copending Application No. 10/375,451. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain the same planar membrane comprising the same elements including substantially-smooth, substantially uniform, about 10-300 microns in thickness, non-porous, resorbable within 24 months,

and made of poly-lactide copolymer. Also, the claims of the instant application claim a method for promoting healing of damaged tissue after an open heart surgery which reads on bone as it is well known that sternum must be cut through during open heart surgery. There is a lack of unexpected results because one of ordinary skill in the art would be motivated to implant the planar membrane adjacent to damaged tissue whether it is bone or pericardial tissue and expect the tissue would regenerate. Thus, it would have been obvious for one of ordinary skill in the art to use the same membrane to heal various tissues.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** Claim 11 is drawn to a method for promoting healing of damaged tissue after an open heart surgery comprising an anti-scar forming agent including angiotensin antagonists. The original

disclosure does not include teachings of a method to include anti-scar forming agents including angiotensin antagonists. The claims within this rejection are examined as written by the applicant; at this time new matter must be considered as part of the claimed subject matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-11 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn et al. (USPN 6,136,333). Cohn teaches a method for reducing adhesions associated with post-operative surgery comprising affixing a polymeric composition to a site in the body which has been subjected to trauma, e.g. by surgery (abstract). Cohn teaches that the polymeric composition is biodegradable, bioabsorbable, comes in various forms including films and cylinders, and capable of

delivering bioactive agents (columns 1-2; column 29, line 49 – column 30, line 2). Cohn also teaches that the films in particular are homogeneous, uniform in thickness and density, and exhibit sufficient strength and flexibility to be able to conform to a site in a patient (column 2, lines 56-59; column 31, lines 52-55). Cohn teaches particular polymers of lactide including poly(L-lactic acid) and poly(D,L-lactic acid), caprolactone, and trimethylene carbonate (column 3, lines 45-64). Also, example 1 shows the thickness of the film to be approximately 10 mils. Cohn is silent to the particular limitations of a resorbable time period of 18-24 months, the percentage of 70:30 poly(L-lactide-co-D,L-lactide); and sterile packaging. It is the position of the examiner that these limitations lack unexpected results because one of ordinary skill in the art would be motivated to test the film and vary the ingredients and thickness in order to optimize the resorbable time period through routine experimentation. Also, it is well known that the surgical materials are sterilized prior to packaging or while packaged by way of, for example, irradiation. One would be motivated to provide the membrane in a sterile package for two main reasons: 1) ease of storage and transportation and 2) reduce the chance of infection in a patient. Thus, in Cohn it would have been obvious for one skilled in the art to include the limitations of a resorbable time period of 18-24 months, the percentage of 70:30 poly(L-lactide-co-D,L-lactide); and sterile packaging.

Pertinent Art

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a: Totakura et al. (USPN 5,795,584) teaches a surgical adhesion barrier (and methods thereof) comprising a bioabsorbable polymers and copolymers including trimethylene carbonate, lactide and caprolactone, and mixtures thereof (abstract; column 3, lines 36-51). The adhesion barrier has a thickness in the range of about 0.1-100 mils and is capable of comprising a medicinal agent (column 5, lines 37-42; column 5, lines 25-52). Also, the barrier is resilient, flexible, and conformable allowing a surgeon to shape the device to fit the area of injury (column 4, lines 58-63; column 10, lines 54-60).

b. Roby (USPN 6,315,788 B1) teaches a composite that may be formed in the shape of a sheet comprising a core and shell for the use as a medical device or implantable surgical devices (abstract). Figure 2A in the Roby patent illustrates a substantially smooth, substantially uniform, planar membrane. Roby also teaches that the sheet may act as an adhesion barrier, enhance tissue ingrowth, and wound healing; may comprise bioabsorbable polymers and copolymers of lactide, polycaprolactone, trimethylene carbonate, and blends thereof; have a core thickness of about 0.001-5.0 mm and shell thickness of about 0.01-0.25 mm (columns 3-4).

Conclusion

10. All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on M-F from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Casey Hagopian
Examiner
Art Unit 1615

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